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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Application Number	09/966893
Filing Date	September 28, 2001
First Named Inventor	d'Azzo
Art Unit	1646
Examiner Name	To be assigned
Attorney Docket Number	SJ-01-0020

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Sheet 1 of 5

## US PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication or issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Name of Inventor(s)
		Number-Kind Code <sup>2</sup> (if known)			
CJA ↓	AA1	US-5,179,023	01-12-1993	Research Corp. Tech. Inc.	Calhoun et al.
	AB1	US-5,658,567	09-19-1997	Research Corp. Tech. Inc.	Calhoun et. al.
	AC1	US-5,762,939	06-09-1998	MG-PMC, LLC	Smith et. al.
	AD1	US-6,183,987	02-06-2001	Stichting Instituut voor Dierhouderij en Diergexonhe	van de Weil et. al.
	AE1	US-6,225,060	05-01-2001	Onyx Pharmaceuticals, Inc	Clark et. al.
	AF	US-			
	AG	US-			
	AH	US-			
	AI	US-			
	AJ	US-			
	AK	US-			

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Page, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
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Christopher J. Tronde

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Sheet 2 of 5

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**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

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CJA	AR1	AEED, P.A. <i>et al</i> , "Glycosylation of recombinant prorenin in insect cells: the insect cell line Sf9 does not express the mannose 6-phosphate recognition signal", <i>Biochemistry</i> 33(29):8793-97 (1994)	
	AS1	AOKI, M. <i>et al</i> , "Improvement of neurological symptoms by enzyme replacement therapy for Gaucher Disease Type IIIb", <i>Eur. J. Pediatr.</i> , 160(1): 63-64 (2001)	
	AT1	BERG, T. <i>et al</i> , "Purification and characterization of recombinant human lysosomal alpha-mannosidase", <i>Mol Genet Metab.</i> , 73(1):18-29 (2001)	
	AU1	BIJSTERBOSCH, M.K. <i>et al</i> , "Quantitative analysis of the targeting of mannose-terminal glucocerebrosidase: Predominant uptake by liver endothelial cells", <i>Eur. J. Biochem.</i> , 237:344-349 (1996)	
	AV1	BONTEN, E J. <i>et al</i> , "Lysosomal Protective Protein/Cathepsin A" <i>Journal of Biological Chemistry</i> 270(44): 26441-26445 (1995)	
	AW1	BONTEN, E J. <i>et al</i> , "Catalytic Activation in Insect Cells is Controlled by the Protective Protein/Cathepsin A", <i>Journal of Biological Chemistry</i> 275(48): 37657-37663 (2000)	
	AX1	BONTEN, E J. <i>et al</i> , "Correction of lysosomal PPCA and neuraminidase in mouse deficient macrophages after uptake of recombinant baculovirus-expressed proteins", <i>Amer. J. Hum. Gen. Suppl.</i> 69(4):Abst 1759 (2001)	
	AY1	BOOSE, J.A. <i>et al</i> , "Synthesis of a human lysosomal enzyme, beta-hexosaminidase B, using the baculovirus expression system", <i>Protein Expr. Purif.</i> 1(2):111-20 (1990)	
	AZ1	BROMME, D. <i>et al</i> , "High level expression and crystallization of recombinant human cathepsin S", <i>Protein Sci.</i> , 5(4):789-91 (1996)	
	AR2	CALHOUN, D.H. <i>et al</i> , "Fabry disease: Isolation of a cDNA clone encoding human $\alpha$ -galactosidase A", <i>PNAS</i> 82:7364-68 (1985)	
	AS2	CHEN, Y. <i>et al</i> , "Purification and Characterization of Human $\alpha$ -Galactosidase A Expressed in Insect Cells Using a Baculovirus Vector", <i>Protein Expression and Purification</i> 20:228-236 (2000)	
	AT2	COPPOLA, G. <i>et al</i> , "Characterization of glycosylated and catalytically active recombinant human alpha-Galactosidase A using a baculovirus vector", <i>Gene</i> 144(2):197-203 (1994)	
	AU2	D'AZZO, A., "Biochemical properties of PPCA and neuraminidase", Presentation at Strategies for Therapy of MPS and Related Diseases and 16 <sup>th</sup> Annual MPS Conference held on June 22, 2001 at UCLA	
	AV2	DAVIDSON, D.J. <i>et al</i> , "Oligosaccharide Processing in the Expression of Human Plasminogen cDNA by Lepidopteran Insect ( <i>Spodoptera frugiperda</i> ) Cells", <i>Biochemistry</i> 29(23): 5584-5590 (1990)	
	AW2	DAVIDSON, D.J. <i>et al</i> , "Asparagine-Linked Oligosaccharide Processing in Lepidopteran Insect Cells. Temporal Dependence of the Natures of the Oligosaccharides Assembled on Asparagine-289 of Recombinant Human Plasminogen Produced in Baculovirus Vector Infected <i>Spodoptera frugiperda</i> (IPBL-SF-21AE) Cells", <i>Biochemistry</i> 30(25): 6167-6174 (1991)	
	AX2	DAVIS, T.R. <i>et al</i> , "Intrinsic Glycosylation Potentials of Insect Cell Cultures and Insect Larvae", <i>In Vitro Cell. Dev.Biol.</i> 31:659-663 (1995)	
	AY2	DESNICK, R.J. "Enzyme replacement and beyond", <i>J Inherit Metab Dis.</i> 24(2):251-65 (2001)	
	AZ2	ENG, C.M. <i>et al</i> , "A phase 1/2 clinical trial of enzyme replacement in fabry disease: pharmacokinetic, substrate clearance, and safety studies", <i>Am. J. Hum. Genet.</i> , 68(3): 711-22 (2001)	
	AR3	HAHN, C.N. <i>et al</i> , "Correction of murine galactosialidosis by bone marrow-derived macrophages overexpressing human protective protein/cathepsin A under control of the colony-stimulating factor-1 receptor promoter", <i>PNAS</i> 95:14880-85 (1998)	

Examiner Signature	<i>Christa L. Tunde</i>	Date Considered	3/18/03
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		<b>Application Number</b>	09/966893
		<b>Filing Date</b>	September 28, 2001
		<b>First Named Inventor</b>	D'Azzo
		<b>Art Unit</b>	1646
		<b>Examiner Name</b>	To be assigned
		<b>Attorney Docket Number</b>	SJ-01-0020
Sheet	3	of	5

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caj	AS3	HOLLISTER, J.R. <i>et al</i> , "Engineering lepidopteran insect for sialoglycoprotein production by genetic transformation with mammalian $\beta$ 1,4-galactosyltransferase and $\alpha$ 2,6-sialyltransferase genes", <i>Glycobiology</i> 11: 1-9 (2001)	
	AT3	HSU, T. <i>et al</i> , "Differential N-Glycan Patterns of Secreted and Intracellular IgG Produced in <i>Trichoplusia ni</i> cells", <i>Journal of Biological Chemistry</i> 272(14): 9062-9070 (1997)	
	AU3	IDA, H. <i>et al</i> , "Effects of enzyme replacement therapy in thirteen Japanese pediatric patients with Gaucher Disease", <i>Eur. J. Pediatr.</i> 106(1): 21-5 (2001)	
	AV3	IOANNOU, Y.A. <i>et al</i> , "Fabry disease: preclinical studies demonstrate the effectiveness of alpha-galactosidase a replacement in enzyme-deficient mice", <i>Am. J. Hum. Genet.</i> 68(1): 14-25 (2001)	
	AW3	JARVIS, D.L. <i>et al</i> , "Biochemical Analysis of the N-Glycosylation Pathway in Baculovirus-Infected Lepidopteran Insect Cells", <i>Virology</i> 212: 500-511 (1995)	
	AX3	JARVIS, D.L. <i>et al</i> , "Modifying the insect cell N-glycosylation pathway with immediate early baculovirus Expression vectors", <i>Nature Biotechnology</i> 14:1288-1292 (1996)	
	AY3	JARVIS, D.L. <i>et al</i> , "Engineering N-glycosylation pathways in the baculovirus-insect cell system", <i>Current Opinion In Biotechnology</i> 9: 528-533 (1998)	
	AZ3	JARVIS, D.L. <i>et al</i> , "Mutational Analysis of the N-Linked Glycans on <i>Autographa californica</i> Nucleopolyhedrovirus gp64", <i>Journal of Virology</i> 72(12): 9459-9469 (1998)	
	AR4	JARVIS, D.L. <i>et al</i> , "Novel baculovirus expression vectors that provide sialylation of recombinant glycoproteins in lepidopteran insect cells", <i>J. Virol.</i> 75(13): 6223-27 (2001)	
	AS4	KAKKIS, E.D. <i>et al</i> , "Enzyme-replacement therapy in mucopolysaccharidosis I", <i>N. Engl. J. Med.</i> 344(3): 182-188 (2001)	
	AT4	KAULI, R. <i>et al</i> , "Delayed Growth in Puberty in Patients with Gaucher Disease Type 1: Natural History And Effects of Splenectomy and/or Enzyme Replacement Therapy", <i>Isr. Med. Assoc. J.</i> 2(2): 158-63 (2000)	
	AU4	KAWAR, Z. <i>et al</i> , "Insect cells encode a class II $\alpha$ -Mannosidase with Unique properties", <i>J. Biol. Chem.</i> 276(19): 16335-40 (2001)	
	AV4	LEW, D.B. <i>et al</i> , "Mitogenic effect of lysosomal hydrolases on bovine tracheal myocytes in culture", <i>J. Clin. Invest.</i> 99: 1969-1975 (1991)	
	AW4	LEW, D.B. <i>et al</i> , "A mannose receptor mediates mannosyl-rich glycoprotein-induced mitogenesis in bovine airway smooth muscle cells", <i>J. Clin. Invest.</i> 94:1855-1863 (1994)	
	AX4	LICARI, P.J. <i>et al</i> , "Insect Cell Hosts for Baculovirus Expression Vectors Contain Endogenous Exoglycosidase Activity", <i>Biotechnol. Prog.</i> 9:146-152 (1993)	
	AY4	LIN, L. <i>et al</i> , "Production and characterization of recombinant human CLN2 protein for enzyme-replacement therapy in late infantile neuronal ceroid lipofuscinosis", <i>Biochem J.</i> 357: 49-55 (2001)	
	AZ4	LIU, Z. <i>et al</i> , "TNF- $\alpha$ and IL-1 $\alpha$ induce mannose receptors and apoptosis in glomerular mesangial but not endothelial cells", <i>Am. J. Physiol.</i> 270: C1595-1601 (1996)	
	AR5	LUTZ, D.A. <i>et al</i> , "Natural, high-mannose glycoproteins inhibit ROS binding and ingestion by RPE cell cultures", <i>Exp. Eye Res.</i> 61: 487-493 (1995)	
	AS5	MAGNUSSON, S. <i>et al</i> , "Endocytosis of ricin by rat liver cells <i>in vivo</i> and <i>in vitro</i> is mainly mediated by mannose receptors on sinusoidal endothelial cells", <i>Biochem J.</i> 291: 749-755 (1993)	
	AT5	MARCHAL, I. <i>et al</i> , "Glycoproteins from insect cells: Sialylated or Not?", <i>Biol. Chem.</i> 382(2): 151-159 (2001)	

Examiner Signature	<i>Christa L. Thonde</i>	Date Considered	3/18/03
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CAJ	AU5	MARTIN, B.M. <i>et al</i> , "Glycosylation and processing of high levels of active human glucocerebrosidase in Invertebrate cells using a baculovirus expression vector", <i>DNA</i> 7(2): 99-106 (1988)	
	AV5	OGONAH, O.W. <i>et al</i> , "Isolation and Characterization of an Insect Cell Line Able to Perform Complex N-Linked Glycosylation on Recombinant Proteins" <i>Biotechnology</i> 14: 197-202 (1996)	
	AW5	PASTORES, G.M. <i>et al</i> , "Enzyme-replacement therapy for Anderson-Fabry disease", <i>Lancet</i> , 358(9282): 601-603 (Aug. 25 2001)	
	AX5	REIS eSOUSA, C. <i>et al</i> , "Phagocytosis of antigens by langerhans cells in vitro", <i>J. Exp. Med.</i> 178: 509-519 (1993)	
	AY5	ROULIEUX-BONNIN, F. <i>et al</i> , "Transcriptional expression of mannose receptor gene during differentiation of human macrophages", <i>Biochem. Biophys. Res. Comm.</i> 217: 106-112 (1995)	
	AZ5	RUDENKO, G. <i>et al</i> , "Three-dimensional structure of the human protective protein; structure of the precursor Form suggests a complex activation mechanism", <i>Structure</i> 3(11): 1249-1259 (1995)	
	AR6	RUDENKO, G. <i>et al</i> , "The atomic model of the human protective protein/cathepsin A suggests a Structural basis for galactosialidosis", <i>PNAS</i> 95: 621-625 (1998)	
	AS6	SALLUSTO, F. <i>et al</i> , "Dendritic cells use macropinocytosis and the mannose receptor to concentrate macromolecules in the major histocompatibility complex class II compartments: Downregulation by cytokines and bacterial products", <i>J. Exp. Med.</i> 182: 389-400 (1995)	
	AT6	SCHIFFMANN, R. <i>et al</i> , "Enzyme replacement therapy in Fabry Disease: a randomized controlled trial", <i>JAMA</i> , 285(21): 2743-2749 (2001)	
	AU6	SEO, N. <i>et al</i> , "Mammalian glycosyltransferase expression allows sialoglycoprotein production by baculovirus-infected insect cells", <i>Protein Expr. Purif.</i> 22(2): 234-41 (2001)	
	AV6	SHEPARD, V.L. <i>et al</i> , "Isolation and characterization of a mannose receptor from human pigment epithelium" <i>Invest. Ophthalmol. Vis. Sci.</i> 32(6): 1779-1784 (1991)	
	AW6	SLY, W.S. <i>et al</i> , "Active site mutant transgene confers tolerance to human beta - glucuronidase without affecting the phenotype of MPS VII mice", <i>PNAS</i> 98(5): 2205-10 (Feb 27, 2001)	
	AX6	STAHL, P.D. <i>et al</i> , "The mannose receptor is a pattern recognition receptor involved in host defense", <i>Current Opinion in Immunology</i> 10: 50-55 (1998)	
	AY6	STEED, P.M. <i>et al</i> , "Characterization of recombinant human cathepsin B expressed at high levels in baculovirus", <i>Protein Science</i> 7(9): 2033-37 (1998)	
	AZ6	STEHLE, S.E. <i>et al</i> , "A Soluble Mannose Receptor Immunoconjugate Enhances Phagocytosis of <i>Pneumocystis Carinii</i> by Human Polymorphonuclear Leukocytes <i>In Vitro</i> ", <i>Scandinavian Journal of Immunology</i> 52: 131-137 (2000)	
	AR7	TAYLOR, M.E., "Structure and Function of the Macrophage Mannose Receptor", <i>Results and Problems in Cell Differentiation</i> 33:105-121 (2001)	

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Christina L. Honda

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Sheet 5	of	5	Attorney
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